

Application No. 10/039,892  
Page 9 of 12

## BEST AVAILABLE COPY

### REMARKS

Applicant has amended claim 1 to recite that the applicator is capable of generating pressures of at least 1000 psi. Consequently, claim 38 has been cancelled. Additionally, claim 1 has been amended to recite that the first column is large enough to accommodate a volume greater or equal to the volume of implant material to be delivered, on average, to a vertebral body during a vertebroplasty procedure.

Regarding the objections to the claims, Applicant has amended claims 15, 20 and 21 as suggested in the Office Action.

#### Examiner Interview

Applicant also wishes to express his appreciation for the Examiner's time and effort to conduct a telephonic interview with Applicant's in-house attorney Richard Batt on August 13, 2004. Mr. Batt discussed claims 1 and 38-42 during the interview as well as cited references U.S. Pat. Nos. 4,863,072 and 5,603,701. Mr. Batt submitted that these patents show low pressure assemblies as opposed to high pressure assemblies. The devices in each of these patents do not appear to be robust enough to inject materials at pressures of upwards of 1000 psi. For example, the single handed dispenser shown in the '072 patent includes a disk shaped end portion that is joined to a plunger 14 via a thin bridge member. It is unclear how a single handed dispenser could be manipulated to generate forces of 1000 psi. Additionally, the thin member 14 does not appear to provide the strength needed to withstand 1000 psi pressure generation.

Mr. Batt also discussed the syringe apparatus shown in the '073 patent. This patent provides a mechanism to automatically allow the plunger to withdraw so as to reduce the pressure exerted by the plunger means. Similar to the '072 device, the head 80 at the proximal end is joined to the plunger with a thin threaded shaft 76. The threads are not dense which suggests large forces are not required. Likewise, the thin shaft joining the end portion to the threaded shaft suggests that the device is not subject to large forces.

Mr. Batt also submitted that syringes used in dental applications are not intended nor subject to great forces and consequently, the dental syringes do not need to be as robust as the injectors used in vertebroplasty.

Application No. 10/039,892  
Page 10 of 12

Mr. Batt also discussed the various structures in Applicant's invention that provide for high pressure delivery. Indeed, a number of combinations may be provided including thread spacing, diameter size, handle shape, and materials.

Finally, Mr. Batt indicated to the Examiner that he would submit a response and amendment.

### Section 102 Rejections

Claims 1-4, 15-18, 20-23, 25-27 and 38-42 stand rejected under 35 U.S.C. Section 102(b) as being anticipated by U.S. Patent 4,863,072 to Perler (hereafter referred to as "Perler").

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." MPEP § 2131 *citing* Verdegaal Bros. V. Union Oil Co. of California, 814 F.2d 628, 631 (Fed. Cir. 1987).

As indicated above, Applicant has amended claim 1 to recite two additional claim limitations that are not described or suggested in Perler. First, claim 1 recites an applicator having a "first column having a volume greater or equal to the volume of implant material to be delivered, on average, to a vertebral body during a vertebroplasty procedure". As indicated in the application on page 3, lines 1-4, 3.5 cc of material may be injected into each side of the vertebral body. The injector as recited in claim 1 thus requires a column having sufficient volume to accomplish this type of injection. Perler does not disclose a device having this size of barrel.

Additionally, the large volume injector must be capable of generating high pressures of 1000 psi or more. As discussed in the interview and memorialized above, the cited patents do not teach high pressure injections, much less large volume high pressure injectors.

Based on the foregoing, withdrawal of the rejection of claim 1 is respectfully requested. The other claims rejected based on Perler depend from claim 1 and are also submitted to be patentable over Perler. Withdrawal of the rejection is therefore requested.

Application No. 10/039,892  
Page 11 of 13

Claims 1 and 24 stand rejected under 35 U.S.C. Section 102(b) as being anticipated by U.S. Patent 5,603,701 to Fischer (hereafter referred to as "Fischer").

Fischer likewise does not disclose each and every claim limitation found in claim 1. Fischer does not disclose a high pressure applicator capable of generating pressures of 1000 psi that can also hold a volume of material sufficient to carry out a vertebroplasty. Fischer provides that the device may be used for dental applications. A relatively small volume of material is necessary to fill a tooth. Teeth may also be filled at very low pressures since various tooth-filling materials are UV curable. Due to the small volumes to be dispensed at low pressures, the dental applicator may be manipulated with only one hand. This is markedly different than the vertebroplasty injector as recited in claim 1.

Additionally, the threads shown in Fischer do not appear to provide increased force. The threads shown in Fischer are not densely spaced. The threads shown in Fischer appear to serve a metering function rather than a force-multiplying function. Indeed, there is no need to make the Fischer device capable of generating higher pressures or more robust.

It is also noteworthy that Applicant's recited claim 1 includes a handle that provides a mechanical advantage upon grasping said handle. This claim limitation provides structure to make the applicator capable of generating high pressures. One hand grasps the handle while the other hand manipulates the second column. This two handed effort provides capability of generating high pressures exceeding 1000 psi and having large enough volumes to perform vertebroplasty procedures.

Based on the foregoing withdrawal of the rejection of claim 1 is requested. Claim 24 depends from claim 1 and is therefore also submitted to be patentable over Fischer.

#### Section 103 Rejections

Claim 19 stands rejected under 35 U.S.C. Section 103(a) as being unpatentable over Perler in view of U.S. Patent 4,032,118 to Phillips.

As indicated above Perler does not teach all claim limitations recited in amended claim 1. A proper *prima facie* case of obviousness under Section 103 requires, amongst other things, that the reference (or references when combined) must teach or suggest all the claim limitations. MPEP § 2142. In this instance, Phillips does not make up for the deficiencies of Perler. No combination of the cited references teach or suggest the invention recited in claim 1. Claim 19

Application No. 10/039,892

Page 12 of 13

indirectly depends from claim 1. Accordingly reconsideration and withdrawal of the rejection of claim 19 under Section 103 is respectfully requested.

Double Patenting Rejection

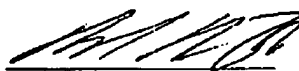
Regarding the rejection based on double patenting, Applicant shall consider filing a terminal disclaimer upon indication that the claims are otherwise allowable.

Application No. 10/039,892  
Page 13 of 13

### IN CLOSING

Applicant believes that all issues raised in the Office Action have been addressed and that the claims are allowable. If the Examiner believes a telephone conference would expedite prosecution of this application, a telephone call to the undersigned attorney at below listed number will be appreciated.

Respectfully submitted,



Richard R. Batt  
Reg. No. 43,485

OCTOBER 4, 2004

Date

ArthroCare Corporation  
680 Vaqueros Avenue  
Sunnyvale, California 94085-3523  
(408) 736-0224

**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

**BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**